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EDMUND M JASKIEWICZ
1730 M STREET NW
SUITE 400
WASHINGTON, DC 20036

EXAMINER	
GRUN, JAMES LESLIE	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 08/981,665
Filing Date: November 05, 1997
Appellant(s): CIPKOWSKI, STAN

B. Aaron Schulman
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 07 September 2010 appealing from the Office action mailed 28 December 2009.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

16, 18, and 19.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner. The rejection of claims 16, 18, and 19 under 35 U.S.C. § 112, second paragraph, has been withdrawn by the examiner.

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

WO 88/08534	MAY et al.	11-1988
5,238,652	SUN et al.	08-1993
4,518,565	BOGER et al.	05-1985
5, 500,375	LEE-OWN et al.	03-1996
5,976,895	CIPKOWSKI	11-1999

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Rejections under 35 U.S.C. § 112, first paragraph

Claims 16, 18, and 19 are rejected under 35 U.S.C. § 112, first paragraph, for reasons of record as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As set forth with regard to the claims as now amended, the specification, as originally filed, does not provide support for a sample **contacting** portion **on the exposed surface** (i.e., front) **of the test strip** so that liquid sample flows through the sample opening in the thin flat member strip holder and contacts the **exposed surface** (i.e., front) of the sample portion exposed beneath (i.e., registering with) the opening. Again, as set forth, appellant provides no guidance in the specification for certain particulars of the test strip structure such that a sample contacting portion of the test strip is necessarily on the exposed surface. Again, appellant merely discloses that specimen is able to contact the "absorbent or sample portions" of the test strips through the

sample openings of the card (see e.g. page 12). There is no disclosure that these portions are necessarily on, or only on, the exposed surface of the test strip. Moreover, there is no specific teaching in the instant specification regarding whether the instantly exemplified test strips do or do not include the optional conventional backing or sandwiching with plastic as taught in May et al. (WO 88/08534). Such sandwiching would affect the size and shape of the "sample portion" and, as taught in some conventional test strip references (see e.g. Lee-Own et al., US 5,500,375), the "sample portion" may only be the cut end and, therefore, not necessarily located on the front surface of a test strip. An absorbent portion, and sample received thereby, can contact the underside of a linked test strip as shown in Figs. 10 or 12 of May et al. (WO 88/08534). Thus, there is nothing to support that the "sample contacting portions" of the test strips are necessarily exposed on the test strip **surface** beneath the opening in the thin flat member as is now claimed. The sample portions are exposed, but there is no disclosure that the sample portions necessarily contact sample on the front surfaces of the test strips. Inclusive disclosure of several formerly commercially available test strips does not provide explicit or implicit indication to one of skill in the art that the invention was contemplated as necessarily limited to particular undisclosed structural interrelationships selected from a range of possible designs. The case of In re Ruschig (379 F.2d 990, 154 USPQ 118 (CCPA 1967)) makes clear that one cannot disclose a forest in the original application, and then later pick a tree out of the forest and say "here is my invention." In order to satisfy the written description requirement, the blaze marks directing the skilled artisan to that tree must be in the originally filed disclosure. See id. at 994-95, 154 USPQ at 122; Fujikawa, 93 F.3d at 1570-71, 39 USPQ2d at 1905; Martin v. Mayer, 823 F.2d 500, 505, 3 USPQ2d 1333, 1337 (Fed. Cir. 1987). Further, the disclosure that the test strip "consists of a

membrane strip onto which a drug conjugate has been immobilized" (see page 13) is not dispositive of the issue because further components of the test strip are either previously or later recited (e.g. colloidal gold-antibody complex, a control band or line, absorbent portion, etc.) so that it is clear that appellant did not intend "consists of" in this context as limiting the test strip structure to a membrane without backing or sandwiching layers or without an appended absorbent portion, conventional alternatives in test strip design as taught in May et al. (WO 88/08534). Indeed appellant teaches test strip alternatives to the disclosure of page 13 such that a line indicates a positive reaction (see e.g. page 10) as an alternative to the disclosed negative reaction (see e.g. page 13). Moreover, the examiner would note that essentially the entire test strip contacts sample (see e.g. specification page 13 wherein it is admitted that urine sample contacts the test line having immobilized drug conjugate) so that a "sample contacting portion" would not appear to be clearly described in the specification. In a related patent, US 5,976,895, it is noted that a sample "receiving" portion is claimed. If it is appellant's intent that the entire bottom portion of the test strip up to the maximum line is to be construed as the now recited "sample contacting portion" because that is the portion submerged in sample (see e.g. page 9 and item 32 in Fig. 3) whether it is sandwiched with plastic or not, whether there is an appended absorbent portion or not, then it is clear that the openings in the test card as depicted in Figs. 9 or 11 do not fully expose (i.e. register with) "the sample contacting portion" because the "MAX LINE" defining the boundary of the sample contacting portion is not within the exposed portion. Although one of skill in the art might realize from reading the disclosure that absorbent or sample receiving portions on the exposed (i.e., front) **surface** of the test strips are useable in the invention or that a sample contacting portion may be fully exposed by a sample opening, such

possibility of use does not provide explicit or implicit indication to one of skill in the art that such were originally contemplated as necessarily part of appellant's invention and such possibility of use does not satisfy the written description requirements of 35 U.S.C. § 112, first paragraph. Note that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement (See, e.g.: *Lockwood v. American Airlines Inc.* 41 USPQ2d 1961 (Fed. Cir. 1977); *ICU Medical, Inc.* 558 F.3d at 1377; *Regents of the Univ. of Cal.*, 119 F.3d at 1566–67). For the reasons set forth above appellant has not provided sufficient evidence that the written description supports a sample **contacting** portion necessarily **on the exposed surface** of the test strip as is now claimed. Appellant was requested to direct the Examiner's attention to specific passages where support for these newly recited limitations could be found in the specification as filed or was required to delete the new matter.

Rejections under 35 U.S.C. § 103 (a)

Claims 16, 18, and 19 are rejected under 35 U.S.C. § 103 (a) as being unpatentable over May et al. (WO 88/08534) in view of Sun et al. (US 5,238,652), and further in view of Boger et al. (US 4,518,565) for reasons of record repeated below for convenience.

May et al. (WO 88/08534) teach a variety of embodiments of an analytical test device. The device comprises a dry porous carrier, preferably a nitrocellulose membrane in the form of a strip (e.g., pages 5-6), having a sample application zone at the bottom end of the strip (e.g. pages 19, lines 26-27, or page 21, lines 30-35) and having a labelled reagent, freely mobile in the carrier in the moist state, in a first zone proximal to the sample application zone (e.g. page 19) and located upstream from a detection zone on the carrier, the detection zone having unlabelled

specific binding reagent immobilized therein (e.g.: pages 3, 7, or 15-16; Figs. 1 and 2). May et al. teach the use of direct labels such as minute colored particles, such as dye sols, metallic sols and colored latex particles (e.g. page 5, 10, or 16). Such test strip devices are for use in, for example, sandwich or competition immunoassays (pages 4-5 and 16-17) for detection of analytes such as drugs, infectious disease agents, pregnancy/fertility hormones, etc., in aqueous samples such as in a urine sample (e.g., pages 7-8, 17, and 20). The aqueous sample permeates the porous solid phase material by capillary action (e.g. pages 4, 15-16). With the choice of appropriate specific binding reagents, the general applicability of the test strip device is taught (e.g., page 17 or 25). Downstream from the detection zone a control zone may be present having, for example, an immobilized anti-mouse immunoglobulin antibody if the mobile labelled specific binding reagent is one derived from a mouse hybridoma (page 9). The porous carrier may communicate directly with the exterior of a casing (e.g.: page 3; claims 1 or 2) or may be linked to a porous (e.g. bibulous) receiving member to which liquid sample can be applied, e.g. by dipping into sample contained in a vessel (pages 20 or 29), placement into flowing sample (page 24), or by means of a syringe (page 28), and from which the sample can permeate into the porous carrier (e.g., pages 6 and 8-9). The porous carrier may be further linked to a porous pad downstream from the assay zone(s) that serves as a sink for liquid passed through the carrier (e.g., pages 11 or 15, Fig. 1). The dry porous carrier can be "backed" or sandwiched with, for example, one or more plastic sheet(s) to increase its handling strength (e.g., pages 13-14) and/or provide a transparent seal against ingress of moisture or sample (e.g., pages 23 or 27). The test strip can be enclosed in a casing having apertures or holes for sample application and apertures, holes, or windows for result and control observation, the shape of the apertures, holes, or

windows not being critical (e.g., pages 7, 8, 20, 21, 25, 27, or 28). If desired the observation apertures can be provided with transparent inserts (e.g., page 25). In some embodiments the test device can be sandwiched between upper and lower halves of the casing having a flat rectangular shape (e.g., pages 20, 24, or 27, Figs. 3 or 11). In embodiments wherein paper or other similar cellulosic materials are used as the porous receiving member, the reference implies that they are not sufficiently robust when wet to protrude from the casing (e.g., pages 9 or 21, Figs. 3, 7, or 13). A device according to the invention can incorporate two or more separate test strips, each having different reagents thereon to determine a plurality of analytes simultaneously, arranged in parallel in a single device (e.g., page 12). The reference contemplated that combinations and subcombinations of the features of the variously described and depicted test strips and casings formed part of the invention (page 40). In contrast to the invention as instantly disclosed and claimed, May et al. do not specifically teach the immunoassay means for determination of drugs of abuse as instantly disclosed and claimed.

Sun et al. teach membrane strips for competitive immunoassay of drugs of abuse (e.g. columns 5-6) and that the strips for such drug of abuse analytes may be configured in a parallel arrangement for simultaneous testing of multiple analytes (e.g. Fig. 3), at least five analytes in a single device being preferred (e.g. column 2). The reference teaches that the strips can be constructed for alternative competitive immunoassay formats (see e.g. column 10) wherein either: antigen in sample and antigen immobilized on the membrane support compete for binding with mobile latex-labelled antibodies; or, mobile latex-labelled antigen and antigen in the sample compete for binding with antibodies immobilized on the membrane support.

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to have constructed the test strips in the device of May et al. with reagents in a competitive immunoassay format for determination of drugs of abuse wherein antigen in sample and antigen immobilized on the test strip compete for binding with mobile labelled antibodies because May et al. teach the general applicability of their devices for determinations of analytes such as drugs with selection of appropriate binding reagents and Sun et al. teach that such constructions were well known alternatives in the art for determinations of drugs of abuse on immunoassay test strips. It would have been further obvious to one of ordinary skill in the art at the time the instant invention was made to have provided the test strips of May et al. in view of Sun et al. in any alternative casing/holder comprising combinations of features taught by May et al., such as a strip as depicted in Fig. 1 of the reference in a flat rectangular casing as depicted in Fig. 11, because May et al. teach that such combinations are possible and because one would have had ample motivation to select from the alternative casing/holder features taught by the reference with the expectation that such would perform the desired casing/holder function. One would have been motivated to provide a flat rectangular casing such as that depicted in Fig. 11 for a nitrocellulose test strip as depicted in Fig. 1 in view of the teachings in May et al. that the sample receiving portion thereof was not sufficiently robust to protrude from a casing. It would have been further obvious to have arranged a plurality of test strips for different drugs of abuse in parallel in a single device in May et al., as modified, because May et al. teach such arrangements for the simultaneous determination of a plurality of analytes and Sun et al. teach that test strips, which may be configured in a parallel arrangement, for the determination of at least five drug of abuse analytes in a single device is preferred.

The teachings of May et al. in view of Sun et al. are as set forth above and differ from the invention as instantly disclosed or claimed in not teaching specific means for the parallel arrangement of a plurality of test strips in a single casing as desired.

Boger et al. (US 4,518,565) teach a rigid holder for holding multiple dip-and-read reagent test devices such as the test strips illustrated in the figures. Such reagent devices can be dipped into a biological sample, such as urine, to provide a detectable response, such as a color change, as a quantitative or at least semiquantitative indication of a constituent or component in the test sample (see e.g. col. 1). Reagent devices usable in the holder of Boger et al. include those dip-and-read test devices for conducting immunochemical tests (e.g. col. 2, lines 58-62). The holder is provided having a base member and a top member which permit multiple individual test devices to be positioned parallel to one another. The base member can have ridges or other means which facilitate the preferred precise parallel alignment of the reagent test devices in the holder (e.g. col. 3, lines 63-66). The top member has openings, exposing each reagent area on the test devices for the application of specimen or sample and the taking of measurements, which can be any configuration, but are preferably the same configuration as the reagent pads on the reagent devices (e.g. ¶¶ bridging cols. 2-3 and 3-4). The holder of the invention is applicable for multiple reagent devices having either multiple (e.g. Figs. 1-2) or single reagent pads (Fig. 3 and cols. 3-4). Although a single opening 22 for each "single pad" device is set forth in the text, two openings for each of these reagent devices are clearly depicted for this embodiment of the holder (Fig. 3). The holder can be constructed of any suitable material, including various copolymers, plastics, metal, or coated cardboard (see e.g. col. 3, lines 50-62). The top and bottom members may be provided separately, becoming engaged in a suitable fashion after placement of the test

devices thereon or therein, or as a foldable assembly (cols. 3-4). Although other configurations such as a circular holder with test devices radiating out from the center are possible, the preferred rectangular shape of the holder, as depicted in the figures, permits the maximum number of test devices to be inserted into a holder of the smallest possible dimensions (col. 4, lines 24-33). The devices may extend beyond the holder (see Figs.) or the holder can be made long enough to accommodate the test devices in their entirety (col. 4, lines 54-58). The holders may be either disposable or reusable and may be used for storage of test devices after their use for testing (col. 4, lines 14-23, and col. 5, lines 50-53). The entire holder can be dipped into the sample to be tested, or sample can be applied to the reagent pads of the devices in the holder by a convenient means which can be automated (¶ bridging col. 4-5). The holder of the invention has the advantages of convenience, simplicity, relative inexpensiveness, positiveness, effectiveness, durability, accuracy, and directness of action (e.g. col. 5, lines 12-15). Thus the holder meets the stated objects of providing a rigid holder for multiple reagent test devices (col. 2, lines 51-53), for making simultaneous analyses of liquid fluid (e.g. claim 1) such as urine (col. 1, line 30), and for protecting the reagent pads prior to use (e.g. col. 5, lines 33-38). Implicit in the disclosure of the holder is that automated processing of the devices in the holder, although an additional object of the invention, is not required for the use of the holder because the holder is taught as usable with multiple conventional, low cost, test devices having a visual result rather than a more expensive alternative format (e.g. col. 5, lines 18-21). Boger et al. do not specifically teach strips for immunoassay of drugs of abuse.

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to have provided the test strips of May et al. in view of Sun et al. in a

casing/holder of a design such as those taught by Boger et al., constructed of coated cardboard and having ridges or other means which facilitate the preferred parallel alignment of the strips, because one would have had ample motivation to select from known and conventional alternative casing/holder components, such as the ridges defining slots to facilitate parallel test strip arrangement taught by Boger et al., with the expectation that such a known casing/holder design would perform its desired casing/holder and arrangement functions for the desired casing of the test strips of May et al. in view of Sun et al. It would have been obvious to have formed the ridges, defining parallel slots, in the base member for strip alignment, as taught in Boger et al., in May et al., as modified, by any conventional means because one of ordinary skill would have expected a conventional means such as lamination or gluing of multiple layers, molding, or cutting, to form the desired ridges and slots therein for the desired parallel alignment. One would have had ample motivation to have selected from among such conventional known techniques with an expectation of success. Further, it would have been an obvious matter of design choice to have provided closed slots in the embodiment of the holder taught in the reference of Boger et al. for use with the test strips of May et al. as modified wherein the test devices are accommodated in their entirety in order to ensure not only parallel alignment of the devices but also proper alignment of the openings in the top member with the reagent area(s) on each of the test devices for the application of specimen or sample and the taking of measurements. Alternatively, it would have been an obvious matter of design choice to have adhered the test strips to the casing/holder device of May et al., as modified by Sun et al. and Boger et al., because a disposable casing/holder was contemplated, and May et al. teach (e.g., page 23) that the strips are to be held firmly in place, as is conventional in the art, to prevent

shifting of the test strips in the casing/holder device and facilitate proper alignment of the openings in the top member with the reagent area(s) on each of the test devices for the application of specimen or sample and the taking of measurements.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

(10) Response to Argument

Response to arguments regarding rejections under 35 U.S.C. § 112, first paragraph

Appellant's arguments have been fully considered but they are not deemed to be persuasive.

Appellant urges that the disclosures that are also noted by the examiner, at pages 12 and at least in Fig. 9, provide "unambiguous" support for the invention as is now claimed. This is not found persuasive for the reasons of record and as set forth above regarding the deficiencies of these disclosures to necessarily support structural/functional elements specifically of the test strip(s) (attached longitudinally to a thin flat member strip holder) as are now claimed that are entirely lacking description in the specification as filed. Appellant implies that some conventional test strips are configured to have a sample receiving portion on the front surface and that the possibility of use of such configured test strips provides support for the claiming of the instant embodiments. This is not found persuasive because, as set forth, test strips have a broad range of possible designs and the inclusive disclosures of several formerly commercially available test strips, for which no evidence has been provided by appellant of a surface sample contacting portion, have not been found as providing explicit or implicit indication to one of skill

in the art that the invention was contemplated as necessarily limited to the particular undisclosed structural interrelationships as are now claimed selected from the broad range of possible designs. Notwithstanding appellant's implications to the contrary, disclosure of a sample portion exposed by an opening does not provide inherent support for a sample contacting portion on the surface of the exposed portion and does not provide support that the entire sample contacting portion, or only the sample contacting portion, is exposed by the opening. The case of In re Ruschig (379 F.2d 990, 154 USPQ 118 (CCPA 1967)) makes clear that one cannot disclose a forest in the original application, and then later pick a tree out of the forest and say "here is my invention." In order to satisfy the written description requirement, the blaze marks directing the skilled artisan to that tree must be in the originally filed disclosure. See id. at 994-95, 154 USPQ at 122; Fujikawa, 93 F.3d at 1570-71, 39 USPQ2d at 1905; Martin v. Mayer, 823 F.2d 500, 505, 3 USPQ2d 1333, 1337 (Fed. Cir. 1987) ("It is 'not a question of whether one skilled in the art might be able to construct the patentee's device from the teachings of the disclosure .... Rather, it is a question whether the application necessarily discloses that particular device.'") (quoting Jepson v. Coleman, 314 F.2d 533,536, 136 USPQ 647, 649-50 (CCPA 1963)). Further, a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement (See, e.g.: *Lockwood v. American Airlines Inc.* 41 USPQ2d 1961 (Fed. Cir. 1977); *ICU Medical, Inc.* 558 F.3d at 1377; *Regents of the Univ. of Cal.*, 119 F.3d at 1566–67).

Appellant urges that it is irrelevant that the wording of the claims could be subject to a different interpretation. This is not found persuasive because, for the reasons of record and as set forth above, the issue is not the interpretation of the wording of the claims, the issue is whether

the written description, as originally filed, and the evidence provided by appellant sufficiently support that specific structural limitations as are now claimed are necessarily present in the disclosure of the test strips of the test cards. For the reasons of record and as set forth above the totality of the evidence fails to support that the structural interrelationships as are now claimed were necessarily present in the original disclosure of the invention.

Response to arguments regarding rejections under 35 U.S.C. §103 (a)

Appellant's arguments have been fully considered but they are not deemed to be persuasive.

In response to Appellant's arguments that there are no specific suggestions to combine the references, the examiner recognizes that references cannot be arbitrarily combined and that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the common knowledge or common sense generally available to one of ordinary skill in the art. See: *In re Nomiya*, 184 USPQ 607 (CCPA 1975); *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); or, *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). However, there is no requirement that the claimed invention or a motivation to make the modification be expressly articulated in any one or all of the references. The test for combining references is what the combination of disclosures, taken as a whole, would suggest to one of ordinary skill in the art. See: *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); or, *In re McLaughlin*, 170 USPQ 209 (CCPA 1971). References are evaluated by what they suggest to one versed in the art, rather than by their specific

disclosures. See: *In re Bozek*, 163 USPQ 545 (CCPA 1969). A person of ordinary skill in the art, using common knowledge and common sense, is capable of fitting the teachings of multiple references together like pieces of a puzzle, regardless of the specific problem being addressed by the individual references. Any need or problem known at the time of the invention can provide a reason for combining elements of the different references. A person of ordinary skill in the art is also a person of ordinary creativity. In this case, for the reasons of record, ample motivations to combine the references with an extremely reasonable expectation of success have been set forth. As set forth, it would have been obvious to one of ordinary skill in the art at the time the instant invention was made to have constructed the device of May et al., i.e. test strip(s) in a holder, as modified employing combinations of features of the specifically exemplified device embodiments therein as well as the ridges or other means which facilitate the preferred parallel alignment of multiple strips in a rigid holder made of cardboard having reagent area-exposing openings as taught in Boger et al., with reagents in a competitive immunoassay format for determination of drugs of abuse because May et al. teach the general applicability of their devices for determinations of analytes such as drugs with selection of appropriate binding reagents, Sun et al. teach that constructions wherein antigen in sample and antigen immobilized on a test strip compete for binding with mobile labeled antibodies were well known alternatives in the art for determinations of drugs of abuse on immunoassay test strips, preferably with a plurality of test strips for different drugs of abuse configured in a parallel arrangement in a holder for the determination of at least five drug of abuse analytes in a single device, and May et al. and Boger et al. teach flat rigid rectangular holder alternatives with reagent area-exposing openings for parallel aligned test strips which can be immersed in liquid samples, such as urine,

which would have been expected to perform the desired alignment and casing/holder functions. As set forth, one would have had ample motivation to select from known and conventional casing/holder components to hold and arrange test strips, as taught in the combination of May et al. and Sun et al., to provide proper alignment of reagent area-exposing and measurement openings with reagent and measurement areas for use.

Appellant's arguments regarding undisclosed features of the test strip(s) attached longitudinally to the thin flat member strip holder were again not found persuasive for the extensive reasons set forth above, and incorporated herein, under the response to arguments regarding rejections under 35 USC 112, first paragraph. The examiner would again note that certain specifics regarding test strip structural limitations are entirely lacking in the instant specification. Again, there is no disclosure in the instant specification regarding whether the instant test strip does or does not include a linked absorbent pad at the sample receiving portion. Appellant, in this regard, merely discloses that specimen is able to contact the "absorbent or sample portions" of the test strips through the sample openings (see e.g. page 12). Moreover, there is no specific teaching in the instant specification regarding whether the instant test strips do or do not include the conventional optional backing or sandwiching with plastic taught in May et al. Such sandwiching would affect the size and shape of the "sample portion" and, as taught in some conventional test strip references (see e.g. Lee-Own et al., US 5,500,375), the "sample portion" may only be the cut end and not the front surface as alleged by appellant. Coupled with this lack of adequate disclosure of the test strip structure is appellant's assertion that the instant test card comprises an improvement because of the asserted sample contacting portion on the surface of the test strip(s). This is not found persuasive because there is nothing to

support appellant's asserted "improvement." Specifically, appellant clearly admits that the test strips for performance of the immunoassay were commercially available (see Specification pages 8-9). Thus, if the test strips were known and available to the art, any "improvement" deriving from the asserted placement of the sample contacting portion on a front surface of the test strip was not the invention of appellant. For the reasons of record and as set forth above, nothing unobvious is seen in merely providing known test strips in parallel in a holder having proper alignment of openings in a top member thereof with the reagent area(s) on each of the incorporated test strips for the application of specimen or sample and the taking of measurements.

In response to appellant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Notwithstanding appellant's arguments to the contrary, if a single reference had disclosed the invention essentially as claimed, a rejection under 35 U.S.C. §102, not under 35 U.S.C. §103, would have been made. Appellant's arguments against individual aspects of the references which were not relied upon in the rejection and which do not serve to teach away from the invention as a whole, such as particular structural elements of various particular embodiments of the housings/holders of Sun et al. or of the test strips of Boger et al., were not found persuasive. The reference of Sun et al is cited for its specific disclosure of membrane strips containing reagents for competitive immunoassay of drugs of abuse, i.e. the "immunoassay means" on the immunoassay test strips disclosed by appellant's specification, and not for the particularities of the housings chosen by

the reference for the test strips. The provision of a transparent area, i.e. a window, for test result viewing rather than an aperture in the devices of Sun et al. is irrelevant to the instant grounds of rejection. May et al. clearly teach apertures in casings registering with sample receiving portions and apertures or windows registering with test portions of test strips therein. Indeed, appellant uses the terms openings and windows interchangeably in the disclosure for the test portions (pages 12-13). Appellant urges that the reference of Boger et al. does not teach capillary flow immunoassay test strips and therefore is totally unrelated to the instant invention. This is not found persuasive for a number of reasons, particularly in view of the relied upon teachings of May et al. and Sun et al. Moreover the reference of Boger et al. is clearly in a related field of endeavor in that it provides a rigid holder for multiple reagent test devices, including for immunochemical tests, for making simultaneous analyses of a liquid fluid, such as urine, and for protecting the reagent strips prior to use. Further, the reference of Boger et al. is not relied upon for the specifics of its dip-and-read immunochemical test strips, its teachings are cited regarding the clearly relevant means which facilitate the preferred precise parallel alignment of reagent test strips in a rigid holder of the smallest possible dimensions, a holder which has openings exposing each reagent area on the aligned test strip devices for the application of specimen or sample and the taking of measurements, and which can be constructed of coated cardboard or other materials.

In this regard appellant also urges that the reference of May et al. teaches away from the invention as claimed because a specific embodiment of the device of May et al. discussed by appellant uses a linked porous receiving member and because other specific embodiments discussed by appellant only expose and contact the ends of the test strips as the sample receiving

portion rather than the unsupported front surface asserted by appellant. These arguments are not found persuasive for a number of reasons. Firstly, the disclosure of May et al. is not limited to only the specific embodiments argued by appellant. The reference clearly teaches that the porous carrier, i.e. the test strip, may **directly** contact the sample through a sample application aperture in the casing and that an additional porous receiving member is an optional embodiment (see e.g. page 3, or claims). Moreover, it would have been obvious to have provided an aperture in a holder/casing which exposes the sample application area, wherever it is located on the test strip or optional linked porous receiving member, in view of the teachings of May et al. or Boger et al. to provide such an aperture. (It is again noted that Boger et al. teach reagent area-exposing openings in a holder, which can be made of cardboard, for holding multiple test strips.) Thus, it is not clear how one could assert that the reference of May et al. teaches away from sample contacting the test strip at the relevant area. Notwithstanding appellant's arguments to the contrary, there is nothing found in the disclosure of May et al. that excludes bathing an entire sample receiving portion of a dry porous carrier without a porous receiving member, as depicted in Fig. 1, when contacted with a sample in a casing such as that depicted in Figs. 5 or 6 or 11. The examiner would note the opening on the front of the device of Fig. 6, as shown in the cut-away view of Fig. 7. The shape of the apertures and their placement on the end or front of the casing/holder would seem obvious matters of design choice related, in part, to the position of the relevant area(s) on the incorporated test strip(s). For example, notwithstanding appellant's assertions to the contrary, the opening 601 in Fig. 11 is above the absorbent portion of the porous receiving member optionally provided as part of the test strip linked to the porous carrier. For the reasons of record, one would have been motivated to provide a casing such as that depicted in

Fig. 11 for a nitrocellulose test strip as depicted in Fig. 1 in view of the teachings in May et al. that such combinations were possible and that the sample receiving portion thereof was not sufficiently robust to protrude from a casing and one would have expected the combination to function as desired. Further, there is nothing to support appellant's assertions of function of the instant strips and carrier/casing/holder in a "completely opposite" manner from that taught by the references because capillary action also moves the sample from a sample receiving zone through the porous carriers of May et al. (see e.g. page 4) or Sun et al. (see e.g. col. 6), porous carriers, i.e. test strips, which can directly communicate with the casing/holder exterior as taught in May et al. and as well known for a multiple strip holder as taught in Boger et al.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/JAMES L GRUN/
Examiner, Art Unit 1641

Conferees:

/Mark L. Shibuya/
Supervisory Patent Examiner, Art Unit 1641

/Gerald G Leffers Jr., PhD/
Primary Examiner